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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/687,757

10/20/2003

Yoshiharu Sato

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7590

08/31/2004

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EXAMINER

GARBER, CHARLES D

ART UNIT

PAPER NUMBER

2856

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,757

Applicant(s)

SATO ET AL.

Examiner

Charles D. Garber

Art Unit

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 08/10/2004 have been fully considered but they are not persuasive.

Applicant argues on page 8 and 9 that the instant invention differentiates a check chip from a correction chip whereas Roth differentiates a reflectance strip from a reagent strip and that the types of strips do not correspond and that further a correction chip and check chip are both different from a measurement chip, suggesting that the instant invention somehow differentiates three rather than two types of strips.

Firstly, the instant invention only expressly differentiates two types of strips.

Secondly, the relevant teaching from Roth is that blood test devices have strips (chips) used for different purposes and that a structural detail, such as the size and shape of the handle end, may be useful in distinguishing them so they are not misused. It is irrelevant what specific purpose each strip/chip serves with respect to a specific shape so long as they are obviously distinguishable because when the strips/chips having any two different functions are nearly identical "the possibility that the two chips are erroneously used is very high" [Applicant's words]. This is essentially and clearly the problem solved by Roth's characteristically shaped strips as such shape has no purpose in the functional operation of the device.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art (Admission) in view of Roth et al. (US Patent 6,201,607).

Regarding claims 1, 10-12 Admission discloses a check chip having a similar shape to a measuring sensor (paragraph 13). The check chip is to be mounted on a measuring device to check operations of the measuring device for measuring a specified component in a sample using the measuring sensor (paragraph 8).

Figure 7 (b) prior art illustration shows check chip 110 comprising a strip-like sensor body with at least one structural characterizing portion provided thereon in the form of a mound or bump on the surface. The structural characterizing portion of the check chip (item 103) has a shape that can be recognized by the user from the touch, and is provided in a location where the user is considered to pick the check chip up and load it in the measuring device touching the structural characterizing portion of the

check chip. Admission also discloses correction chip 100 (used for calibration) having a similar shape to a measuring sensor and the correction chip being for correcting errors in the measuring device (paragraph 13). Together, these two strips may be considered a kit.

Figure 7(a) prior art shows at least one structural characterizing portion on the strip-like correction chip.

Admission lacks the structural characterizing portion on the portion where the user is considered to pick it up and touch while loading it thus allowing a user of the measuring device to recognize a difference between the strips.

Roth teaches a test strip 18' as shown in figures 11, 12 distinguished from a calibration strip 20" shown in figures 13, 14 by various structural characteristics including differently appearing handle ends shown at the bottom of the figures. Specifically, one handle end is wider than the other. One handle end is thicker than the other. One handle end has an indentation while the other is smooth. All these differences are distinguishable by touch and all these differences are evident on the portion of the stick a user is likely to hold when picking it up and touch while placing it in the test device.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to distinguish different types of strips used in a measurement device based on the structural characteristics so that the wrong strip would not be inserted by mistake or to ensure the strips are inserted in the proper sequence when the user handles them.

As for claim 2, Ross teaches the end (shown at the bottom when figures 11-14 are oriented with figure labels at the top) of each type of strip have different sizes and are advantageous for the same reasons as discussed above.

As for claims 3 and 4, which alternatively provide for the larger vs. smaller sized feature on either chip, Examiner considers it would have been an obvious matter of design choice to combine the features in any particular way to so long as the strips do not resemble each other, since Applicant has not disclosed that the location, size, shape of the structural features assigned to a particular type of strip solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any combination of structural features.

As for claim 5, the number of characterizing structure portions on the test strip taught by Roth may reasonably be considered to be one (that is the notch at the top) while the number of characterizing structure portions on the calibration strip may reasonably be considered to be between two and 5 (from either the top not notched and the bottom with handle to the top with no notch but dished underneath and the bottom with handle-like portion protruding on both sides and out and the handle portion also having an indented arrow portion). The difference between the two strips therefore may be considered to reside in a number of structural characterizing portions thereon and the differences are again advantageous for the same reasons given above.

As for claims 6 and 7, which alternatively provide for the larger vs. smaller quantity of features on either chip, Examiner considers it would have been an obvious matter of design choice to combine the features in any particular way to so long as the

strips do not resemble each other, since Applicant has not disclosed that the location, size, shape or number of the structural features assigned to a particular type of strip solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any combination of structural features.

As for claim 8, the shape of the bottoms or tops of both the test and calibration strips is different as shown by Roth. The top of the test strip has a "V" notch while the top of the calibration strip has a dished back. The bottom of the test strip has a smooth uninterrupted shape while the bottom of the calibration strip has a protrusion extending out the front and sides and the differences are again advantageous for the same reasons given above.

As for claims 13 and 14, the characteristics of the handle portion discussed above with respect to claims 1 and 11 are on a portion of the Roth strips that would not be inserted into the device and are advantageous for the same reasons as discussed above.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art (Admission) as modified by Roth et al. (US Patent 5,995,236) and applied to claim 1 above and further in view of Taylor et al. (US Patent 3,783,345) and Horhold et al. (US Patent 4,308,085).

Admission on page 4 of the specification further discloses the structural characterizing portion of a check chip has a convex shape and has a resistor buried therein. The buried resistor is considered to be inherently indicating a constant

Art Unit: 2856

resistance value as this is the nature of simple (non-adjustable) resistors. Admission lacks the shape comprising epoxy resin containing silica powder.

Taylor teaches embedding electronic components in high silica epoxy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to embed the resistor in high silica epoxy as this is a preferred way of making a heat dissipating assembly.

The references do not expressly teach the silica to be in the form of powder but Horhold teaches admixture of fillers like silica gel (sand or powder-like form of silica) or quartz powder causing volume contraction to be reduced (column 6 lines 10-14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the powder form because it has the effect of reducing unwanted volume contraction upon curing and also reinforces the cured structure.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 2856

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles D. Garber whose telephone number is (571) 272-2194. The examiner can normally be reached on 6:30 a.m. to 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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